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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,479

05/10/2006

Steffen Goletz

GULDE-63

4918

91436

7590

11/26/2010

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EXAMINER

GUSSOW, ANNE

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

11/26/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,479	<b>Applicant(s)</b> GOLETZ ET AL.	
	<b>Examiner</b> ANNE M. GUSSOW	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 79-83, 85-116 and 122-131 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 79-83, 85-87, 89-95 and 97-116 is/are allowed.
- 6) ☒ Claim(s) 88, 96, 130 and 131 is/are rejected.
- 7) ☒ Claim(s) 122-129 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/24/10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 88, 90, 91, 95, 96, 100, 130, and 131 have been amended.  
Claims 1-78, 84, and 117-121 have been cancelled.

2. Claims 79-83, 85-116, and 122-131 are under examination.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on September 24, 2010 was filed after the mailing date of the non-final office action on May 19, 2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this office action.

### ***Objections Withdrawn***

4. The objection to claims 81, 82, 90, 91, 100, and 108-110 is withdrawn in view of applicant's amendment to the claims.
5. The objection to claim 117 is withdrawn in view of applicant's cancellation of the claim.

***Rejections Withdrawn***

6. The rejection of claim 117 under 35 U.S.C. 101 as being directed to non-statutory subject matter is withdrawn in view of applicant's cancellation of the claim.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 88, 96, 130, and 131 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's arguments filed September 17, 2010 have been carefully considered by the examiner but they are deemed not to be persuasive. The response states that Applicants respectfully assert that the person of skill in the art at the time of filing of the present invention would have known that CDRs are amenable to a substantial number of amino acid substitutions without significant effect on antigen binding. They would have been particularly convinced that this is true with respect to the substitution of functionally analogous amino acids. ... Vajdos would also have taught the skilled artisan to believe that minor CDR variation is largely inconsequential with respect to antigen binding. ... De Pascalis showed that not all residues of a CDR are involved in antigen binding. Id. at 3083, left-hand column, second paragraph. In fact, De Pascalis in referencing Padlan et al, notes that "[e]xamination of the known structures of Ab-Ag

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complexes reveals that only one-third of the CDR residues are involved in the interaction with the Ag." Id. at 3080, left-hand column, second paragraph. (see response pages 27-33).

### ***Response to Arguments***

In response to these arguments, regarding Rudikoff, while mutations at some positions do not affect antigen binding, or only slightly decrease antigen binding as argued by applicant, Rudikoff also teaches mutations at positions which does significantly affect antigen binding, namely position 35. Therefore, in this antibody position 35 is essential for binding. Rudikoff does not provide guidance to one of skill in the art as to how to determine which residues are essential and which are non-essential other than a trial and error process. Vajdos teaches that residues which were intolerant to alanine substitutions were also intolerant to homologous substitutions (abstract and pages 424-425). Similarly, De Pascalis identifies SDRs (specificity determining residues) within the CDRs that are essential for antigen binding and Casset used peptide mapping to identify active antigen recognition residues. The instant claims do not identify which amino acid positions within the CDRs are essential for binding. Each of the cited references teaches that some of the CDR residues are essential for binding. Applicant's Exhibit A demonstrates specific mutations at specific positions within the CDR regions, while the claims are drawn to a broader scope of mutation at any position within the CDR region. The specification does not disclose which positions within the CDR regions (or anywhere in the antibody) are essential for antigen binding. One of

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ordinary skill in the art would not be able to determine which residues are essential for binding.

As set forth in the previous office action, amendment of the claims to include the limitations of claims 112-129 in claims 88, 96, 130, and 131 may obviate this rejection.

Therefore after a fresh consideration of the claims and the evidence provided the rejection is maintained.

### ***Conclusion***

9. Claims 88, 96, 130, and 131 are rejected.

Claims 79-83, 85-87, 89-95, and 97-116 appear to be in condition for allowance.

Claims 122-129 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
November 23, 2010

/Anne M. Gussow/  
Primary Examiner, Art Unit 1643